



Introduction to the VALOR Study

August 24, 2022

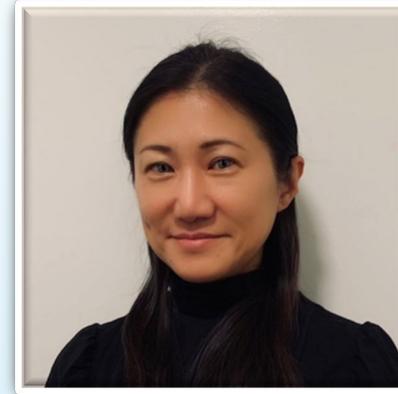
Welcome MSU Community!

Developing targeted therapies for patients with severe autoimmune disease



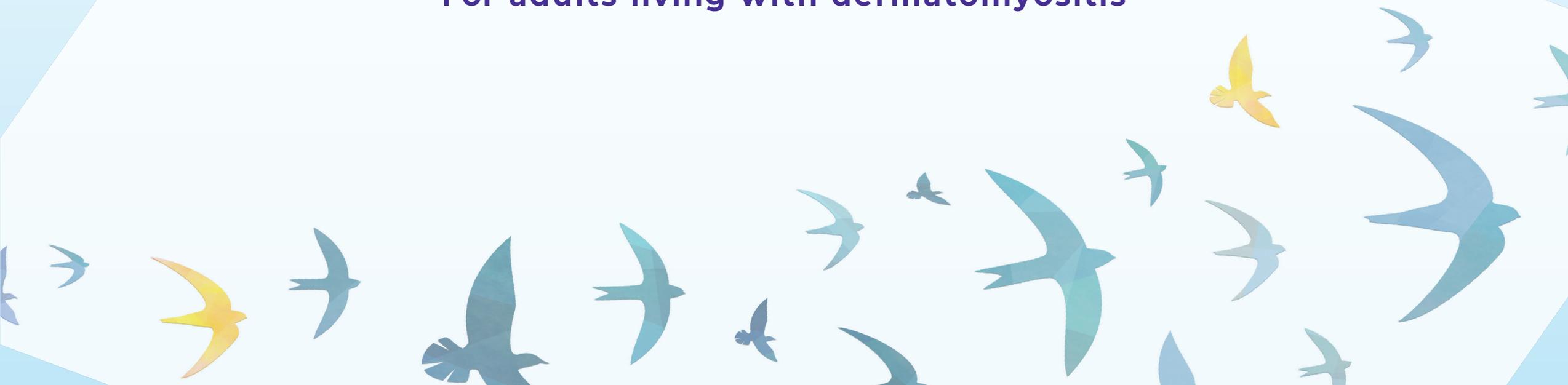
Introductions and Agenda

- Noriko Iikuni, MD, PhD, FACP
Vice President of Clinical Development
- Barbara Zupancic, MBA, MSc
Head Patient Enrollment & Engagement
- Taryn Smith, MHS, PA-C
Patient Evaluation Manager





For adults living with dermatomyositis



- **Brepocitinib** is a tyrosine kinase (TYK) 2/Janus kinase (JAK) 1 inhibitor in an oral tablet
- TYK2 and JAK1 are part of the Janus kinase family of enzymes that are involved in the pathway that causes inflammation in the body
- Inhibiting these two enzymes may block the part of the immune system involved in causing the inflammation seen in dermatomyositis

- **Brepocitinib** has been studied in other autoimmune diseases in phase 2 trials and has shown significant and clinically meaningful results in these studies
- Brepocitinib is also currently being studied in a phase 2 trial for lupus
- The VALOR Study will investigate whether brepocitinib improves signs and symptoms of dermatomyositis

Welcome to the VALOR Study!

This study is for: adults ages 18-74 living with dermatomyositis

Before deciding if you want to take part, it's important to understand:

- ✓ Why the study is being done
- ✓ What happens during the study

What is the purpose of the VALOR Study?

Purpose of the Study:

- ✓ To learn more about the investigational medicine, brepocitinib, in adults living with dermatomyositis.
- ✓ Characterize the safety and tolerability profile of brepocitinib

What happens during the study?

The study lasts up to 64 weeks (15 months) with about 13 visits for tests and health checks.

Screening Period

- Up to 8 weeks
- At least 1 visit

Study Treatment Period

- 52 weeks
- 11 visits

Follow Up Period

- 4 weeks
- 1 visit

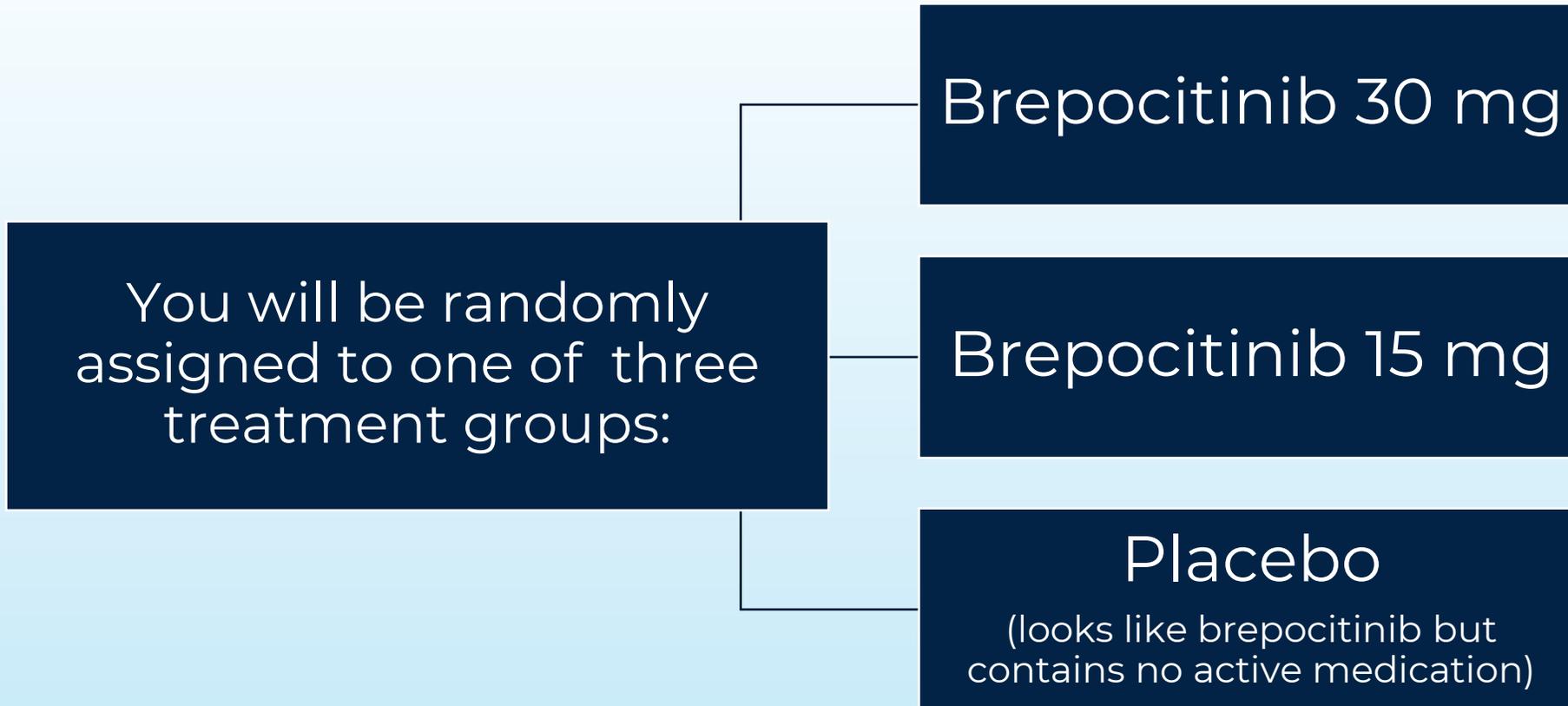
You may have the option to continue in a separate extension study to receive brepocitinib.

What happens during the screening visit?

- Give permission to join
 - ✓ Read the Participant Information Sheet and ask any questions you may have of the study physician
 - ✓ Give your permission to join the study by signing the Informed Consent Form
- Health information collected
 - ✓ Medical and health history
 - ✓ Medicine review
 - ✓ Demographic information
- Tests and health checks
 - ✓ Muscle testing and disease categorization
 - ✓ Questionnaires
 - ✓ Physical exam
 - ✓ Vital signs
 - ✓ Height
 - ✓ Weight
 - ✓ Blood test
 - ✓ Urine test
 - ✓ Heart activity
- Possible additional tests
 - ✓ Imaging scan (CT or PET-CT scan)
 - ✓ Lung function
 - ✓ Chest x-ray
 - ✓ Photos of skin
 - ✓ Pregnancy test

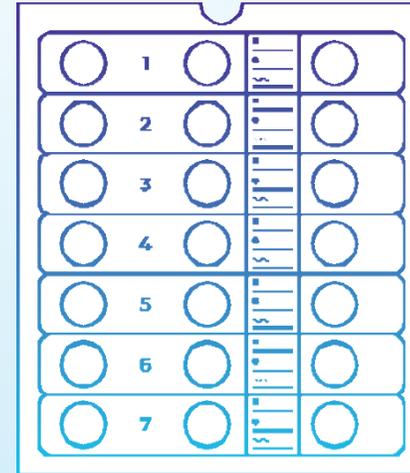
What study treatment will I receive?

You are **twice as likely** to receive study drug as placebo.



How will I take the study drug?

- You will take 3 tablets by mouth every morning. You may take the tablets with or without food.
- **You will continue to receive your current medications in addition to the study drug.**



Can I be treated by the study physician for symptom flares, if needed?

Yes!

What happens at study visits?

Study visit are every 4-6 weeks

- Health checks and tests
 - ✓ Muscle testing and disease categorization
 - ✓ Questionnaires
 - ✓ Physical exam + Vital signs
 - ✓ Weight
 - ✓ Blood test
 - ✓ Urine test
 - ✓ Heart activity
- Health information
 - ✓ Medication review
- Possible additional tests
 - ✓ Lung function tests
 - ✓ Photos of the skin
 - ✓ Pregnancy test

What are some possible benefits and risks to being in the study?

Possible benefits

- You may experience a reduction in your symptoms of dermatomyositis.
- Information learned may help others with dermatomyositis.
- You will have access to study-related medical care during the study.

Possible risks

- You may have unwanted side effects from the study drug and/or study procedures.
- Absolute confidentiality of your medical records and data cannot be guaranteed.
- Other unknown risks because brepocitinib is investigational.
- Other risks may exist – please see informed consent document at screening visit.

Will it cost me anything to be in the study?

It will not cost you anything to participate in the study.

You may be able to get reimbursed for your travel costs to and from the study site.

Speak to a member of the study team for more information.

VALOR study website – valorstudy.com

valor
study

About The Study | [FAQ](#) | [For Sites](#) ▾ | [Join The Study](#)

Rise Above Dermatomyositis with VALOR

The VALOR Study is a clinical study for adults (from 18 to 74 years old) with dermatomyositis who are not finding symptom relief with current treatment.

[Check Eligibility](#) [▶ Watch Video](#)

What is the VALOR Study testing?

The VALOR Study is testing an investigational medicine called

What is dermatomyositis?

Dermatomyositis is a rare disease in which the immune system mistakenly attacks the skin and muscles. This causes muscle

Fill out a short form



Thank You for Your Interest in the VALOR Study!

We'd like to match you with a [healthcare provider from our team](#), who can speak with you personally to help determine whether you'd be a good fit for the VALOR Study, answer any questions you might have, and guide you through the sign-up process. We just need a little information from you to get started.

Your privacy is important to us — your information will be kept confidential and will only be used to help us determine your potential eligibility.

- Do you have Dermatomyositis?** Yes No ⓘ
- What is your date of birth?** ⓘ
- Do you live in the United States?** Yes No ⓘ
- Are you completing this form for yourself or for someone else?** Someone Else Self

Next step...



Thank You for Your Interest in the VALOR Study!



Thank you! Based on your answers you may be eligible to participate in the VALOR Study.

Taryn Smith, PA-C, a member of the VALOR Study team, is trained as a healthcare provider and will tell you more about the VALOR Study, answer any questions you may have, and help determine whether you would be eligible for further screening. You can use the calendar below to make an appointment or have a [scheduling link sent](#) to you to set up a video call with her.

The call will take approximately 30 minutes. The times listed below are in the Central Time timezone.

If you have questions about the pre-screening process, please visit our [FAQs](#).

Sunday 8/7/22	Monday 8/8/22	Tuesday 8/9/22	Wednesday 8/10/22	Thursday 8/11/22	Friday 8/12/22	Saturday 8/13/22
∅	08:00 AM	08:00 AM	08:00 AM	08:00 AM	08:00 AM	∅
	08:30 AM	08:30 AM	08:30 AM	08:30 AM	08:30 AM	
	09:00 AM	09:00 AM	09:00 AM	09:00 AM	09:00 AM	
	09:30 AM	09:30 AM	09:30 AM	09:30 AM	09:30 AM	
	10:00 AM	10:00 AM	10:00 AM	10:30 AM	10:30 AM	
	10:30 AM	10:30 AM	10:30 AM	11:30 AM	11:00 AM	
	11:00 AM	11:00 AM	11:00 AM	12:00 PM	11:30 AM	
	11:30 AM	11:30 AM	11:30 AM	12:30 PM	12:00 PM	

If you would rather not schedule a video call and would instead prefer to have Taryn Smith, PA-C contact you, please click one of the buttons below:

Email me instead

Call me instead

Valor Study materials for patients' understanding and support

Recruitment Poster

Informed Consent Flip Chart

Welcome to the VALOR Study!

You are being asked to take part in this study because you have dermatomyositis.

This information is taken from the Participant Information Sheet, which tells you about the study. Please read the information sheet carefully. Ask any questions you have and discuss this study with family or friends before deciding whether you want to take part.

Please do not sign the Informed Consent Form until you:

- Understand the goals of this study.
- Understand the procedures and risks involved.
- Have been informed of your rights.
- Agree to take part in this study.

You don't have to be in the study. Taking part in the study is voluntary.

If you decide to take part in this study, you will be asked to sign the Informed Consent Form before any study procedures begin.

Discussion Question

Before we continue, do you have any questions about why you have been invited to join the study?

Welcome to the VALOR Study!

This study is for adults with dermatomyositis.

Before deciding if you want to take part, it's important to understand:

- Why the study is being done
- What happens during the study

Ask any questions you have. Being in the study is up to you!

Study Schedule

What happens during the Screening Period?

Study Visit 1 (Scheduled date/time)

Now that you have given permission to join the study by reading the patient information sheet and signing the Informed Consent Form, the study doctor will contact information and run tests to make sure the study is right for you.

Health information collected: Medical and health history, Medication, Comorbidities, Allergies, Current symptoms, Demographics, Physical exam, Vital signs, Height, Weight, Blood tests, Urine tests, Blood work, Chest X-ray, Lung function, etc.

What happens during the Study Treatment Period?

Study Visits 2 to 12 (11 visits over 52 weeks)

These are tests and health checks you will have during the next 11 study visits. You will not have all of these tests at every visit.

Health information collected: Medical and health history, Medication, Comorbidities, Allergies, Current symptoms, Demographics, Physical exam, Vital signs, Height, Weight, Blood tests, Urine tests, Blood work, Chest X-ray, Lung function, etc.

Tests and health checks: Physical exam, Vital signs, Height, Weight, Blood tests, Urine tests, Blood work, Chest X-ray, Lung function, etc.

You will be continuously monitored throughout the study for any side effects.

Informed Consent Video

Understanding the valor study

A clinical study for adults living with dermatomyositis

Patient Letters

Are you satisfied with your current dermatomyositis treatment?

If you are still experiencing symptoms of dermatomyositis with your current treatment, you may be interested in learning about a clinical study sponsored by Pivovant Therapeutics.

The VALOR Study is evaluating an investigational medicine called brepocitinib to see if it may improve symptoms of dermatomyositis in adults 18 to 74 years old.

How long is the study?

Screening Period	Study Treatment Period	Follow-up Period
Up to 8 weeks	52 weeks (1 year)	4 weeks

Once you complete the Study Treatment Period, you may have the option to continue in an extension study. If you are eligible and choose to take part, you will not be required to complete the Follow-up Period.

Why should I participate?

- If you are eligible and decide to participate, you will:
 - Receive study-related treatments and care at no cost.
 - Be monitored by study doctors who specialize in dermatomyositis.
 - Join others in helping to advance research for dermatomyositis.

Participation is voluntary, and if you decide to join, you can choose to stop at any time.

If you would like to learn more about the VALOR Study, contact:

To learn more about the VALOR Study, go to www.ValorStudy.com

Looking for a different treatment option for your dermatomyositis?

If you are still experiencing symptoms of dermatomyositis with your current treatment, you may want to consider the VALOR Study.

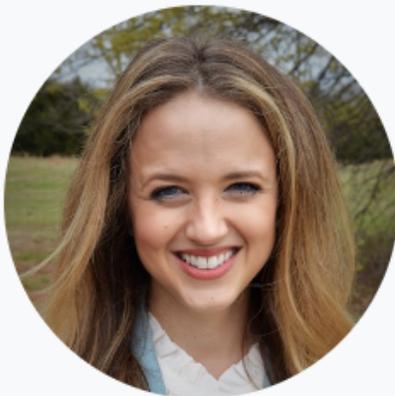
investigational symptoms of 18 to 74 years old.

Your health will be closely monitored by a doctor who specializes in dermatomyositis.

and visit www.ValorStudy.com



Our Patient Evaluation Manager



Taryn Smith, PA-C, VALOR Study Patient Evaluation Manager, is an experienced clinician with almost a decade of experience caring for patients.

By entering your information and following the process here, you can set up a videoconference (or phone call or email exchange, if you prefer) with Taryn so she can tell you more about the VALOR study, help you understand whether you'd be eligible to participate, and guide you through the process of enrolling at a site.

OK

- Single point of contact
- Experienced & friendly
- Concierge-level service from first contact to study site



valorstudy.com
patientsupport@priosanttx.com